Complete Summary

GUIDELINE TITLE

Practice management guidelines for the management of venous thromboembolism in trauma patients.

BIBLIOGRAPHIC SOURCE(S)

EAST Practice Parameter Workgroup for DVT Prophylaxis. Practice management guidelines for the management of venous thromboembolism in trauma patients. Winston-Salem (NC): Eastern Association for the Surgery of Trauma (EAST); 2001. 63 p. [146 references]

Rogers FB, Cipolle MD, Velmahos G, Rozycki G, Luchette FA. Practice management guidelines for the prevention of venous thromboembolism in trauma patients: the East practice management guidelines work group. J Trauma 2002 Jul;53(1):142-64. [146 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Venous thromboembolism (VTE)
- Deep venous thrombosis (DVT)
- Pulmonary embolism (PE)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Evaluation
Management

Prevention
Risk Assessment

CLINICAL SPECIALTY

Emergency Medicine
Neurological Surgery
Orthopedic Surgery
Radiology
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for the management of venous thromboembolism in trauma patients

TARGET POPULATION

Trauma patients aged 14 and older

INTERVENTIONS AND PRACTICES CONSIDERED

Prophylaxis

1. Low-dose heparin (considered)
2. Arteriovenous foot pumps (considered)
3. Sequential compression devices (considered)
4. Low molecular weight heparin
5. Vena cava filters

Treatment

1. Vena cava filters

Diagnosis

1. Ultrasonography
2. Venography

MAJOR OUTCOMES CONSIDERED

- Efficacy of treatment options to prevent venous thromboembolism (i.e., incidence of deep vein thrombosis [DVT]/pulmonary embolism [PE] in treatment groups)
- Complications of prophylactic regimens and treatment options, for example the incidence of major and minor bleeding complications in treatment groups
- Diagnostic accuracy of ultrasound, and venography to detect deep vein thrombosis in symptomatic and asymptomatic patients as measured by sensitivity and specificity

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Risk factors for venous thromboembolism after injury:

Three literature databases were searched (MEDLINE, EMBASE, and Cochrane Controlled Trials Register) for articles reporting on risk factors of venous thromboembolism.

The use of low-dose heparin for deep vein thrombosis/pulmonary embolism prophylaxis:

A Medline review from 1966 to the present revealed several hundred articles related to the use of low dose heparin in medical and general surgical patients.

The role of arteriovenous foot pumps in the prophylaxis of deep vein thrombosis/pulmonary embolism in trauma patients:

A Medline review dating back to 1980 revealed 12 articles on A-V foot pumps. There were eight articles specifically related to the use of A-V foot pumps in the trauma patient.

The use of sequential compression devices in the prevention of deep vein thrombosis/pulmonary embolism:

A Medline search from 1986 to the present produced a large number of articles on this topic. Those articles pertinent to trauma-related thromboembolism prevention were reviewed.

The role of low molecular weight heparin in venous thromboembolism prophylaxis in trauma patients:

Medline searches and personal review of the literature revealed hundreds of articles examining the use of low molecular weight heparin in venous thromboembolism prophylaxis. Two meta-analyses, both published in 1992,

regarding the "older" literature on the use of low molecular weight heparin in general surgery and orthopedic surgery populations were summarized. The important recent Class I studies that have appeared in the English literature were reviewed.

The role of the vena cava filter in the prophylaxis and treatment for pulmonary embolism:

A Medline search from 1980 to 1999 showed ten articles when "vena cava filter" was cross-referenced with "trauma". An additional personal review of the literature revealed seven additional articles and two abstracts that addressed extended indications of vena cava filter placement in trauma patients. Also, there were four articles that specifically addressed complications and long-term follow up with vena cava filters which are included in this review.

The role of ultrasound in diagnostic imaging for deep vein thrombosis in trauma:

A Medline search from 1966 to present revealed several thousand articles related to the ultrasound diagnosis of deep vein thrombosis. Several of the more seminal articles and review articles related to the ultrasound diagnosis of deep vein thrombosis in the non-trauma patient are included to provide a perspective on the current state of the technology.

The role of venography in the diagnosis of deep vein thrombosis in trauma patients:

A Medline search from 1966 to present identified 3,520 articles related to venography in the diagnosis of deep vein thrombosis.

NUMBER OF SOURCE DOCUMENTS

Risk factors for venous thromboembolism after injury: 73 source documents

The use of low-dose heparin for deep vein thrombosis/pulmonary embolism prophylaxis: 8 source documents

The role of arteriovenous foot pumps in the prophylaxis of deep vein thrombosis/pulmonary embolism in trauma patients: 12 source documents

The use of sequential compression devices in the prevention of deep vein thrombosis/pulmonary embolism: 23 source documents

Prophylactic use of low molecular weight heparin for venous thromboembolism in trauma patients: Not stated

The role of the vena cava filter in the prophylaxis and treatment for pulmonary embolism: 21 source documents

The role of ultrasound in diagnostic imaging for deep vein thrombosis in trauma: 16 source documents

The role of venography in the diagnosis of deep vein thrombosis in trauma patients: 8 articles plus some seminal review articles

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Class I evidence: Prospective randomized controlled trials (PRCTs) - the gold standard of clinical trials. Some may be poorly designed, have inadequate numbers, or suffer from other methodological inadequacies.

Class II evidence: Clinical studies in which the data were collected prospectively, and retrospective analyses which were based on clearly reliable data. These types of studies include observational studies, cohort studies, prevalence studies and case control studies.

Class III evidence: Studies based on retrospectively collected data. Evidence used in this class includes clinical series, database or registry review, large series of case reviews, and expert opinion.

Technology assessment: The assessment of technology, such as intracranial pressure (ICP) monitoring devices, does not lend itself to classification in the above-mentioned format. Thus, for technology assessment, the devices are evaluated in terms of their accuracy, reliability, therapeutic potential, and cost-effectiveness.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Overall: Class I articles were evaluated according to the validity scale described by Jadad et al (Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, McQuay HJ. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials 1996 Feb;17[1]:1-12). The articles were graded on a 5 point system: was the study described as randomized (0 or 1), was the study described as double-blind (0 or 1), was there a description of withdrawals and drop outs (0 or 1), was the randomization appropriate (-1 or 1), was the blinding appropriate (-1 or 1)). Articles with a score <3 were considered to have poor design and/or methodology and were considered by the subcommittee in formulating final recommendations. For Class II and III articles,

objective validation scales do not exist. Each of these articles was read by at least two members of the panel in order to evaluate design and method.

Subsequent to this, a quality assessment was performed. Quality was evaluated by assessing if a hypothesis was set forth, the methods were well described and adhered to, the results were accrued according to the described methods and the conclusions supported by the results and addressed the hypothesis. After this, the reviewer provided a final classification of the article and comments. Both the classification and quality of the data were considered in the final determination of the recommendations. Differences of opinion with regards to an article´s classification, relevance or quality were arbitrated by the panel chairperson.

As the articles were assessed, an evidentiary table was compiled containing the following columns: first author, year of publication, reference title and journal citation, classification, and conclusions taking into account the design, methods, and quality of the article.

See the companion document titled Utilizing Evidence Based Outcome Measures to Develop Practice Management Guidelines: A Primer.

Risk Factors for Venous Thromboembolism After Injury: All articles were reviewed by two independent reviewers and a third reviewer in cases of disagreement. The review was done against predetermined screening criteria, and the articles were given a numerical quality score.

Pooled effect sizes (odds ratio [OR] and their 95% confidence intervals were estimated by the DerSimonian and Laird random effects model. Shrinkage graphs were produced to display the effect size of each study and compare it with the overall model estimate. The heterogeneity among studies was tested by the Q-statistic and P value for the chi-square test of heterogeneity. A level of significance at $P<0.05$ was used for all comparisons.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Four practice management guidelines, including "Practice management guidelines for the management of venous thromboembolism in trauma patients," were developed by the Eastern Association for the Surgery of Trauma (EAST) Ad Hoc Committee for the Development of Practice Management Guidelines for Trauma.

A consensus conference of 20 trauma surgeons interested in guideline development was held and initial topics were selected for development. Each member of the conference selected topics that they felt were important for development. Four topics were then selected by majority consensus. Each topic was assigned a chairperson, and the chairperson was then responsible for selecting his/her committee members. The individual committees were given latitude on how to approach their topics but all were expected to conform to the

EAST step-by-step process of practice management guideline development. Once completed, the guidelines were reviewed by the committee chairperson and the chairperson of the guideline committee and returned for revision

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Level I: The recommendation is convincingly justifiable based on the available scientific information alone. This recommendation is usually based on Class I data, however, strong Class II evidence may form the basis for a Level I recommendation, especially if the issue does not lend itself to testing in a randomized format. Conversely, low quality or contradictory Class I data may not be able to support a Level I recommendation.

Level II: The recommendation is reasonably justifiable by available scientific evidence and strongly supported by expert opinion. This recommendation is usually supported by Class II data or a preponderance of Class III evidence.

Level III: The recommendation is supported by available data but adequate scientific evidence is lacking. This recommendation is generally supported by Class III data. This type of recommendation is useful for educational purposes and in guiding future clinical research.

COST ANALYSIS

Low Molecular Weight Heparin (LMWH)

There have been three studies which have examined the cost-effectiveness of using a relatively expensive therapy, ie LMWH, in hip replacement surgery. Taking into account the reduction in deep vein thrombosis (DVT) with similar or lower bleeding risk and the ability to administer LMWH without following coagulation, it has been shown to be more cost-effective than standard heparin.

Ultrasound Diagnosis of DVT in the Trauma Patient

One group of researchers performed a cost analysis of routine screening for proximal DVT using color-Doppler ultrasound in 116 head-injured patients being admitted to a rehab unit over a 21-month period. Fourteen (8.5%) patients were found to have DVT on initial screening. No confirmatory studies were performed, and all were asymptomatic. The authors conducted a complicated cost-benefit analysis of ultrasound screening for DVT in this population and found that the cost per year of life saved was $2,977.65 ($129,527.83/43.5years). This compared favorably to the $8,280 per year of life saved for biennial mammograms for women age 50-59 and the $35,054 per year of life saved for annual fecal occult blood tests beginning at age 65. As is indicative of such an analysis, there are a number of underlying assumptions which may not reflect reality, nevertheless it does lend perspective on the cost issues relative to other screening programs.

A second group of researchers examined the cost effectiveness of biweekly ultrasound screening versus placement of prophylactic vena cava filters (VCF) on reducing pulmonary embolism (PE) in high risk trauma patients using a decision tree type of analysis. The authors found that ultrasound was more cost effective

than VCF with a cost per PE prevented of $46,3000 vs $97,000. However, ultrasound screening became more expensive than VCF when the anticipated length of stay was greater than or equal 2 weeks. Again there are a number of assumptions that underlie such a decision tree analysis that may not reflect clinical reality. In contrast, a third group of researchers concluded that the cost ($18,586 per DVT identified) of routine screening did not justify its use in patients receiving routine prophylaxis.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A final document was drafted by the panel presenting a synthesis of the literature review and the opinion of the panel members. The draft document was then submitted to all members of the panel for review and modification. Subsequent to this the guidelines were forwarded to the chairman of the Eastern Association for the Surgery of Trauma ad hoc committee for guideline development. Final modifications were made and the document forwarded back to the individual panel chairpersons.

The guidelines were then presented to Eastern Association for the Surgery of Trauma membership. This may have been accomplished by oral presentation at the national meeting or via the Internet. This allowed the members an opportunity to ask questions, make suggestions, and improve the guidelines. Approximately 3 months after presentation, final revisions were made and the guidelines were submitted to the Guideline Editorial Review Board. The board is made up of members of the American Association for the Surgery of Trauma. The purpose of the review was to assure that the recommendations are supported by the evidence, that all the evidence pertinent to the guideline was collected, and to offer expert opinion in areas where there is debate or lack of adequate data. The revised document was then sent back to panel chairpersons and the chairman of the guideline committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Risk Factors for Venous Thromboembolism After Injury

The existing evidence supports the presence of two risk factors of post-traumatic venous thromboembolism: spinal fractures and spinal cord injuries. Older age is an additional risk factor but it is not clear at which exact age the risk increases substantially. There is inadequate literature evidence to support that other frequently reported risk factors, such as long-bone fractures, pelvic fractures or head injuries, really increase the risk for venous thromboembolism. There is a need for additional research in this area.

A. Level I

1. Patients with spinal cord injuries or spinal fractures are at high risk for venous thromboembolism following trauma

B. Level II
    1. Older age is an increased factor for venous thromboembolism but it is not clear at which exact age the risk increases substantially.
    2. Increasing injury severity score and blood transfusion do appear to be associated with a high risk of venous thromboembolism in single institution studies, however, on meta-analysis these factors did not prove of major significance.
    3. Likewise traditional risk factors such as long bone fractures, pelvic fractures or head injuries in many studies may constitute a high-risk patient population in single institution studies but on meta-analysis it did not prove of major significance.

The Use of Low Dose Heparin for Deep Vein Thrombosis/Pulmonary Embolism Prophylaxis

The overall effectiveness of low dose heparin for the prophylaxis of venous thromboembolism in trauma patients remains unclear. Most studies show no effect of low dose heparin on venous thromboembolism. Most studies on the use of low dose heparin in trauma patients suffer from severe methodologic errors, poor study design, and small sample size, suggesting the possibility of a type II statistical error.

A. Level I

There are insufficient data to support a standard on this subject.

B. Level II

There is little evidence to support a benefit of low dose heparin as a sole agent for prophylaxis in the trauma patient at high risk for venous thromboembolism.

C. Level III

For patients in whom bleeding could exacerbate their injuries (such as those with intracranial hemorrhage, incomplete spinal cord injuries, intraocular injuries, severe pelvic or lower extremity injuries with traumatic hemorrhage, and intra-abdominal solid organ injuries being managed nonoperatively), the safety of low dose heparin has not been established, and an individual decision should be made when considering anticoagulant prophylaxis.

The Role of Arteriovenous Foot Pumps in the Prophylaxis of Deep Vein Thrombosis/Pulmonary Embolism in Trauma Patients

Small clinical series in elective orthopedic patients support the use of arteriovenous foot pumps to prevent deep vein thrombosis. Only one clinical series in trauma patients compares arteriovenous foot pumps to other standard techniques of deep vein thrombosis prophylaxis. The results from this series are not definitive in terms of the benefits of arteriovenous foot pumps in preventing

deep vein thrombosis. However, there is a theoretical advantage for the use of arteriovenous foot pumps in the high-risk trauma patient who has a contraindication to heparin because of their injuries and who cannot have sequential compression devices placed on lower extremities secondary to external fixators or large bulky dressings.

A. Level I

There are insufficient data to suggest Level I recommendations for this topic.

B. Level II

There are insufficient data to suggest Level II recommendations for this topic.

C. Level III

Arteriovenous foot pumps may be used as a substitute for sequential compression devices in those high-risk trauma patients who cannot wear sequential compression devices due to external fixators or casts.

The Use of Sequential Compression Devices in the Prevention of Deep Vein Thrombosis/Pulmonary Embolism

The use of sequential compression devices worn on the lower extremity in patients at high risk for deep vein thrombosis and to reduce the rate of deep vein thrombosis is widely accepted, however, clinical studies demonstrating their effectiveness in trauma patients are few. While the exact mechanism of action of sequential compression devices is not known, their effect is felt to be based on a combination of factors addressing stasis and hypercoagulability. Until these mechanisms are better studied and understood, answers to specific questions regarding the appropriate use of sequential compression devices are forthcoming.

A. Level I

There are insufficient data to support a standard on this topic.

B. Level II

There is insufficient data at this time that sequential compression devices decrease the risk of venous thromboembolism in multiply injured patients.

C. Level III

1. In the subset of spine-injured head-injured patients, sequential compression devices may have some benefit in isolated studies.
2. For patients in whom the lower extremity is inaccessible to place sequential compression devices at the calf level, foot pumps may act as an effective alternative to lower the rate of deep vein thrombosis formation.

The Role of Low Molecular Weight Heparin in Venous Thromboembolism Prophylaxis in Trauma Patients

There is a wealth of Class I data supporting the use of low molecular weight heparin as venous thromboembolism prophylaxis in orthopedic surgery. This literature is derived primarily from total hip and knee replacement patients. Overall, low molecular weight heparin appears to be equivalent or superior to unfractionated heparin for prophylaxis in general surgery patients. There is now Class I data inferring that low molecular weight heparin is superior to unfractionated heparin for prophylaxis in moderate to high-risk trauma patients. However, selection of venous thromboembolism prophylaxis in trauma patients can be a challenging balance between venous thromboembolism risk and bleeding risk. Most data in many different types of patients confirm improved efficacy of low molecular weight heparin with the same or even less bleeding risk compared to unfractionated heparin prophylaxis. Low molecular weight heparin should be the standard form of venous thromboembolism prophylaxis in trauma patients with complex pelvic and lower extremity injuries as well as spinal cord injuries. The Class I data would imply that low molecular weight heparin should be strongly considered for use in all high risk trauma patients when their bleeding risk is acceptable.

A. Level I

There are insufficient data to make Level I recommendations for general use of low molecular weight heparin as venous thromboembolism prophylaxis in trauma patients.

B. Level II

Low molecular weight heparin could be used for venous thromboembolism prophylaxis in trauma patients with the following injury patterns:

1. Pelvic fractures requiring operative fixation or prolonged bed rest (>5 days)
2. Complex lower extremity fractures (defined as open fractures or multiple fractures in one extremity) requiring operative fixation or prolonged bed rest (> 5 days)
3. Spinal cord injury with complete or incomplete motor paralysis

The use of low molecular weight heparin is predicated on the fact that these patients do not have other injuries that put them at high risk for bleeding.

C. Level III

1. Trauma patients with an injury severity score >9, who can receive anticoagulants, should receive low molecular weight heparin as their primary mode of venous thromboembolism prophylaxis.
2. The use of low molecular weight heparin or oral anticoagulants for several weeks post-injury should be considered in patients who remain at high risk for venous thromboembolism [i.e., elderly pelvic fracture patients, spinal cord injury patients, patients who remain at prolonged bed rest (>5 days), and patients who require prolonged hospitalization or rehabilitation].
3. Low molecular weight heparin has not been sufficiently studied in the head-injured patient with intracranial bleeding to justify its use at this time.

4. Low molecular weight heparin should not be in use when epidural catheters are placed or removed.

The Role of the Vena Cava Filter in the Prophylaxis and Treatment of Pulmonary Embolism

There is no Class I literature to support insertion of a vena cava filter in a trauma patient without an established deep vein thrombosis or pulmonary embolism. There is starting to accumulate a fair amount of Class II and III data which may support its use in "high-risk" trauma patients without a documented occurrence of a deep vein thrombosis or pulmonary embolism. At this time, the guideline developers recommend consideration of inferior vena cava filter insertion in patients without a documented deep vein thrombosis or pulmonary embolism who meet high-risk criteria and cannot be anticoagulated.

A. Level I

There is a large body of evidence not reviewed in this section to support insertion of a vena cava filter for "traditional" indications in trauma patients. These indications include:

1. Recurrent pulmonary embolism despite full anticoagulation
2. Proximal deep vein thrombosis and contraindications to full anticoagulation
3. Proximal deep vein thrombosis and major bleeding while on full anticoagulation
4. Progression of iliofemoral clot despite anticoagulation (rare)

B. Level II

"Extended" indications for prophylactic vena cava filter placement in a patient <u>with</u> established deep vein thrombosis or pulmonary embolism include:

1. Large free-floating thrombus in the iliac vein or inferior vena cava
2. Following massive pulmonary embolism in which recurrent emboli may prove fatal
3. During/after surgical embolectomy

C. Level III

Insertion of a "prophylactic" vena cava filter should be considered in very high risk trauma patients:

1. Who cannot receive anticoagulation because of increased bleeding risk
2. Have one or more of the following injury patterns:
    a. Severe closed head injury (Glasgow Coma Score <8)
    b. Incomplete spinal cord injury with para or quadriplegia
    c. Complex pelvic fractures with associated long-bone fractures
    d. Multiple long-bone fractures.

Patients at high risk for bleeding complications for 5 to 10 days after injury would include those with intracranial hemorrhage, ocular injury with associated hemorrhage, solid intraabdominal organ injury (i.e.., liver spleen, kidney), and/or

pelvic or retroperitoneal hematoma requiring transfusion. Other risk factors for bleeding include cirrhosis, active peptic ulcer disease, end-stage renal disease, and coagulopathy due to injury, medication, or congenital/hereditary.

The Role of Ultrasound in Diagnostic Imaging for Deep Vein Thrombosis in Trauma

Numerous studies in the non-trauma literature attest to the overall accuracy of both Doppler and duplex ultrasound in the detection of deep vein thrombosis in the symptomatic patient. The overall accuracy of screening ultrasound in the asymptomatic patient is less clear. Many reports on the use of screening ultrasound, (either Doppler or duplex), lack corroboration of accuracy with contrast venography. Of concern is that many of these studies report on pulmonary emboli in the presence of negative screening ultrasound exams, leading one to speculate on the ability of duplex to detect clinically significant deep vein thrombosis.

A. Level I

Duplex ultrasound may be used to assess symptomatic trauma patients with suspected deep vein thrombosis without confirmatory venography.

B. Level II

There are insufficient data to suggest Level II recommendations for this topic.

C. Level III

1. Hand-held Doppler ultrasound may be used to assess symptomatic trauma patients with suspected deep vein thrombosis. Confirmatory venography may be needed in patients who screen positive for deep vein thrombosis with Doppler ultrasound.
2. Serial duplex ultrasound imaging of high-risk asymptomatic trauma patients to screen for deep vein thrombosis may be cost-effective and decrease the incidence of pulmonary embolism. However, the use of ultrasound in screening asymptomatic patients is burdened by a low sensitivity when compared to venography in the short term.

The Role of Venography in the Diagnosis of Deep Vein Thrombosis in Trauma Patients

Although venography traditionally has been the diagnostic modality for deep vein thrombosis by which all other diagnostic modalities have been compared, logistical problems and complications associated with the procedure make it less appealing than other non-invasive diagnostic measures. Nevertheless, it still has a role in confirming deep vein thrombosis in trauma patients when diagnostic studies are equivocal, or possibly, as an outcome measure in clinical trials of thromboprophylaxis efficacy.

A. Level I

There are insufficient data to support a Level I recommendation on this topic.

B. Level II
    1. Ascending venography should be used as a confirmatory study in those trauma patients who have an equivocal impedance plethysmography (IPG) or ultrasound for deep vein thrombosis.
    2. Ascending venography should not be used to screen asymptomatic trauma patients at high risk for deep vein thrombosis. There may be a role for ascending venography in research studies on the incidence of deep vein thrombosis in trauma patients.

C. Level III
    1. Magnetic resonance venography many have a role in diagnosing acute DVT in the trauma patient, especially with clots in the calf and pelvis (areas where venography and ultrasound are less reliable).

Definitions:

The correlation between the evidence and the recommendations is as follows:

Level 1 recommendation: This recommendation is convincingly justifiable based on the available scientific information alone. It is usually based on Class I data, however, strong Class II evidence may form the basis for a level 1 recommendation, especially if the issue does not lend itself to testing in a randomized format. Conversely, low quality or contradictory Class I data may not be able to support a level 1 recommendation.

Level 2 recommendation: This recommendation is reasonably justifiable by available scientific evidence and strongly supported by expert opinion. It is usually supported by Class II data or a preponderance of Class III evidence.

Level 3 recommendation: This recommendation is supported by available data but adequate scientific evidence is lacking. It is generally supported by Class III data. This type of recommendation is useful for educational purposes and in guiding future clinical research.

Class I evidence: Prospective randomized controlled trials (PRCTs) - the gold standard of clinical trials. Some may be poorly designed, have inadequate numbers, or suffer from other methodological inadequacies.

Class II evidence: Clinical studies in which the data were collected prospectively, and retrospective analyses which were based on clearly reliable data. These types of studies include observational studies, cohort studies, prevalence studies and case control studies.

Class III evidence: Studies based on retrospectively collected data. Evidence used in this class includes clinical series, database or registry review, large series of case reviews, and expert opinion.

Technology assessment: The assessment of technology, such as impedance plethysmography (ICP) monitoring devices, does not lend itself to classification in the above-mentioned format. Thus, for technology assessment, the devices are evaluated in terms of their accuracy, reliability, therapeutic potential, and cost-effectiveness.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

General: Evidentiary tables classify citations with regard to the type and quality of scientific evidence (Class I-III; see the "Major Recommendations" field). The type and strength of evidence is correlated to the recommendation based on another rating scheme (Level 1-3, see the "Major Recommendations" field)

Risk factors for venous thromboembolism: The evidentiary table cites four class I, eight class II, and five class III studies.

Low dose heparin: The evidentiary table cites three class I, two class II, and five class III studies.

A-V foot pumps: The evidentiary table cites two class I, six class II, and eight class III studies.

Sequential compression devices: The evidentiary table cites one class I, ten class II, and ten class III studies.

Low molecular weight heparin: The evidentiary table cites addressing the specific use of low molecular weight heparin in trauma patients includes three class I studies and two class II studies.

Vena cava filters: The evidentiary table cites two class I, eleven class II, and sixteen class III studies.

Ultrasound: The evidentiary table cites five class I, six class II, and eight class III studies.

Venography: The evidentiary table cites zero class I, five class II, and seven class III studies.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Effective prophylaxis for venous thromboembolism to reduce the rate of deep vein thrombosis /pulmonary embolism in trauma patients
- Effective treatment of established pulmonary embolism
- Appropriate utilization of ultrasonography, and venography for diagnosis of DVT in trauma patients

Subgroups Most Likely to Benefit:

Risk factors for post-traumatic venous thromboembolism:

- Spinal fractures
- Spinal cord injury
- Older age

POTENTIAL HARMS

Anticoagulation: Bleeding is a potential complication with the use of heparin (low-dose heparin, low-molecular-weight heparin, unfractionated heparin).

Arteriovenous foot pumps: Severe skin changes, including blistering and wound problems, have been reported in patients who wore arteriovenous foot pumps.

Sequential compression devices (SCDs): Compression devices appear to be well-tolerated with minimal side effects. Isolated case reports of pressure necrosis from a too-tightly fitted sequential compression devices have been reported. Also peroneal palsy and compartment syndromes have been reported with sequential compression devices. A potential complication of sequential compression devices is to elevate intracranial pressure in those with severe head injury.

Complications of sequential compression devices have been noted in case reports and have been associated with improper positioning of the lower extremity during surgery which should be avoided.

Inferior vena cava filters: The use of inferior vena cava filters may be associated with both short and long-term complications, including insertion complications (e.g., caval penetration), recurrent pulmonary embolism, inferior vena caval thrombosis/occlusion, and chronic venous insufficiency.

Venography: Although the possibility of contrast-induced deep vein thrombosis exists, the risks of this complication are unknown but likely to be low. Injection of contrast media may result in local skin discomfort, and if significant extravasation occurs, skin necrosis may result.

Subgroups Most Likely to Be Harmed:

Sequential compression devices (SCDs): A potential complication of sequential compression devices is to elevate intracranial pressure in those with severe head injury.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Guidelines are an expected part of medical practice in today's society. However, they cannot be blindly accepted nor considered inviolate. If that were the case they would cease to be guidelines and would become standards or even mandates. Guidelines must be directed primarily toward the well being of the patient.

- There are many unresolved issues concerning venous thromboembolism prophylaxis of trauma patients that need to be studied in a multicenter fashion. Until prospectively validated risk assessment tools are available, the guideline developers urge that each institution adopt local guidelines for venous thromboembolism risk and establish guidelines among the trauma, orthopedic, and neurological surgeons for bleeding risk after trauma.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The final version of the guideline is forwarded to the Journal of Trauma and to the Eastern Association for the Surgery of Trauma Web page.

The guideline developers make the following recommendations regarding implementation:

Implementation involves extensive education and inservicing of nursing, resident, and attending staff members and has one important guiding principle: the guidelines must be available to the clinicians in real time while they are actually seeing the patient. The two most common ways to apply these are by using either a critical pathway or a clinical management protocol. It is felt that in the trauma and critical care setting, clinical management protocols may be more easily applied than critical pathways, however either is acceptable providing that the formulated guidelines are followed. After appropriate inservicing, a pretest of the planned guideline should be performed on a limited patient population in the clinical setting. This will serve to identify potential pitfalls. The pretest should include written documentation of experiences with the protocol, observation, and suggestions. Additionally, the guidelines will be forwarded to the chairpersons of the multi-institutional trials committees of Eastern Association for the Surgery of Trauma, Western Association for the Surgery of Trauma and American Association for the Surgery of Trauma. Appropriate guidelines can then be potentially selected for multi-institutional study. This process will facilitate the development of user friendly pathways or protocols as well as evaluation of the particular guidelines in an outcome based fashion.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

EAST Practice Parameter Workgroup for DVT Prophylaxis. Practice management guidelines for the management of venous thromboembolism in trauma patients. Winston-Salem (NC): Eastern Association for the Surgery of Trauma (EAST); 2001. 63 p. [146 references]

Rogers FB, Cipolle MD, Velmahos G, Rozycki G, Luchette FA. Practice management guidelines for the prevention of venous thromboembolism in trauma patients: the East practice management guidelines work group. J Trauma 2002 Jul;53(1):142-64. [146 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 (revised 2001)

GUIDELINE DEVELOPER(S)

Eastern Association for the Surgery of Trauma - Professional Association

SOURCE(S) OF FUNDING

Eastern Association for the Surgery of Trauma (EAST)

GUIDELINE COMMITTEE

EAST Practice Parameter Workgroup for DVT Prophylaxis

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Workgroup Members: Frederick B. Rogers, MD, FACS; Mark D. Cipolle, MD, PhD; George Velmahos, MD, PhD; and Grace Rozycki, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of this guideline.

This guideline updates a previously released version (EAST practice management guidelines for trauma. Allentown (PA): Eastern Association for the Surgery of Trauma; 1998 Jan 23. p. 66-162).

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Eastern Association for the Surgery of Trauma (EAST) Web site.

Print copies: Available from the EAST Guidelines, c/o Violet Holiday, Administrative Assistant, Wake Forest University School of Medicine, Hypertension Center, Washington Hall, First Floor, Medical Center Boulevard, Winston-Salem, NC 27157. Phone: (336) 716-9865.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Utilizing evidence based outcome measures to develop practice management guidelines: a primer. Allentown (PA): Eastern Association for the Surgery of Trauma; 2000. 18 p. Available from the EAST Web site.

An excerpt is also available:

- Pasquale M, Fabian TC. Practice management guidelines for trauma from the Eastern Association for the Surgery of Trauma. J Trauma 1998 Jun;44(6):941-56; discussion 956-7.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 5, 1999. The information was verified by the guideline developer on June 17, 1999. This summary was most recently updated on April 30, 2002. The updated information was verified by the guideline developer as of May 16, 2002.

COPYRIGHT STATEMENT

Date Modified: 5/10/2004


FIRSTGOV